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Hollow Government:

Resource Constraints and Workload Expansion at the

FOOD AND DRUG ADMINISTRATION

[REDACTED VERSION]

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**Hollow Government:
Resource Constraints and Workload Expansion at FDA**

I. Introduction

It may be true that the “era of big government is over,”¹ but new problems have replaced big government in its wake. The size of government agencies’ staffs and budgets have shrunk to respond to public perceptions of waste and bloat, but the public continues to expect a high level of services from the government. It seems that Americans expect more from government than they have invested in it.² As Rudolph G. Penner, a former director of the Congressional Budget Office, trenchantly asked, “The question is, are taxpayers able

¹President William Jefferson Clinton, 1996 State of the Union Address. Archived at *Public Papers of the Presidents, William J. Clinton—1996*, vol. 1, at 79.

²Mark L. Goldsten. *America’s Hollow Government: How Washington Has Failed the People*. Business One Irwin: Homewood, IL, 1992, at iix.

to reconcile what they have come to expect from government during the past 50 years with any willingness to pay for it?”³

As agencies’ responsibilities have expanded and their resources have remained stagnant, they have been forced to limit—and in some cases even ignore—actions they are legally bound to carry out.⁴ Public administrators, Washington observers, and political scientists have dubbed this new syndrome “hollow government.”⁵ Today, the symptoms of hollow government are widespread in federal agencies, particularly those with regulatory responsibilities such as the Food and Drug Administration (FDA).

Indeed, FDA provides an instructive case study of hollow government.⁶ FDA regulates products that account for 25 percent of the consumer dollars spent in the United States, and it oversees almost a third of the products in US markets.⁷ Furthermore, the markets FDA regulates have exploded in size and complexity over the past twenty years. For example, the number of FDA-regulated shipments of imports entering the United States increased more than six-fold, from less than 1 million in 1979 to nearly 6 million today. Since 1990, public and private sector drug research expenditures have grown seven-fold, from less than \$5 billion to \$35 billion, leading to a 54 percent hike in annual new drug approvals during the 1990s.⁸ See Figure 1.

[figure redacted]

³Mark L. Goldstein. “Hollow Government,” 21 *Government Executive* 10, October 1988, at 13.

⁴Mark L. Goldstein. *America’s Hollow Government: How Washington Has Failed the People*. Business One Irwin: Homewood, IL, 1992, at iix.

⁵See, for example: David Broder, “Hollow Government and Lost Revenue, *Washington Post*, February 18, 1990, at B7; Timothy B. Clarke, “Editor’s Notebook,” *Government Executive*, May 1999, at 4; and Mark Goldstein, *America’s Hollow Government* (Homewood, IL: Business One Irwin, 1992).

⁶See United States Senate Committee on Government Affairs hearing, “Hollow Government: the Food and Drug Administration,” One Hundred Second Congress, first session, July 25, 1991.

⁷Congressional Quarterly, Inc. 1999. *CQ’s Federal Regulatory Directory*, 9th ed., Congressional Quarterly: Washington, D.C., at 214.

⁸Food and Drug Administration FY 2001 Performance Plan. Accessible at: <http://www.fda.gov/ope/fy01plan/parts01.html>.

From 1979 to 1999, medical device technology developed from x-ray machines and CAT scans into robotic surgery, implantable health monitoring devices, and biomaterials. Food standards in 1979 were based on a chemical understanding of the ingredients and additives; now FDA must learn how to regulate genetically-modified foods. Drug discovery in 1979 consisted primarily of chemical and pharmacological understanding of the ingredients; today, technology is at the threshold of microchip screening, and the discovery of drugs is increasingly driven by understanding of the human genome.⁹

Congress has added to the fray, passing dozens of new laws expanding FDA's reach and responsibilities during that period. Among the new laws was, for example, the Infant Formula Act, passed in 1980, which required FDA to set standards for the content and processing of infant formulas.¹⁰ Another law, the Orphan Drug Act of 1983, established a new program within FDA to foster the development of drugs for rare medical conditions.¹¹ Later that year, President Reagan enacted the Federal Anti-Tampering Act, which gave FDA authority to investigate tampering incidents related to products the agency regulates.¹² The Prescription Drug Marketing Act of 1987 charged FDA with restricting the distribution of drug samples, supervising a ban on specific resales of drugs, and policing drug wholesalers.¹³ The AIDS Amendments of 1988 required FDA to establish and maintain a registry of experimental AIDS drugs.¹⁴ The Nutrition Labeling and Education Act ordered FDA to test claims such as "low-fat" or "natural" before a manufacturer could use those terms on food labels, and it gave FDA the responsibility to ensure that packaged foods carry nutrition labels.¹⁵ This sample merely hints at the range of new laws imposing new duties on FDA each year.

Despite its burgeoning workload, however, since 1979 the number of full time equivalent employees (FTEs)

⁹Food and Drug Administration FY 2001 Performance Plan. Accessible at: <http://www.fda.gov/ope/fy01plan/parts01.html>.

¹⁰94 Stat. 1190, 21 U.S.C. 301 note.

¹¹96 Stat. 2049, 21 U.S.C. 1365 note.

¹²97 Stat. 831, 18 U.S.C. 1265 note.

¹³102 Stat. 95, 21 U.S.C. 301 note.

¹⁴102 Stat. 3062, 42 U.S.C. 201 note.

¹⁵104 Stat. 2353, 21 U.S.C. 301 note.

at FDA grew less than 9 percent, from 8,179¹⁶ to 8,910.¹⁷ See Figure 2. In the past twenty years, FDA's budget increased by approximately 50 percent in constant dollars, from \$320 million¹⁸ (\$647 million in 1999 dollars¹⁹) to \$981 million in fiscal year (FY) 1999.²⁰ While this represents a greater increase than most federal agencies received during the same period, it is still manifestly insufficient to accommodate the growth of the responsibilities that have been entrusted with the agency.

[figure redacted]

This paper will examine the phenomenon of hollow government at the Food and Drug Administration during the 1990s. First, it will develop the concept of hollow government, describing its causes and effects and providing examples from other agencies. Next, because it is impossible to grasp the ramifications of organizational hollowing at FDA during the 1990s without understanding how the agency fared during the 1980s, the paper will provide the essential context. Then, it will proceed with a general assessment of the situation of the agency as a whole during the 1990s, followed by an in-depth assessment of changes in the workload and resources at each of the five major program Centers located within FDA. Finally, the paper will interpret the results of the empirical analysis to determine the degree to which FDA has experienced "hollowing" over the past decade.

¹⁶*FDA Fiscal Year 1993 Almanac*, at 61.

¹⁷*FDA Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-8. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹⁸FDA Center for Food Safety and Applied Nutrition. "The Story of the Laws Behind the Labels: Part III 1962 Drug Amendments." June 1981. Posted at: <http://vm.cfsan.fda.gov/~lrd/histor1b.html#toc>.

¹⁹Numbers inflated using the Bureau of Labor Statistics Inflation Calculator, posted at: www.bls.gov.

²⁰*Budget of the United States of America, Analytical Perspectives*, 2000, at 529. Posted at: <http://w3.access.gpo.gov/usbudget/fy2001/pdf/spec.pdf>

II. Hollow Government

In the 1970s, Army Chief of Staff Edward C. Meyer coined the phrase the “hollow Army” to describe how insufficient funding and poor preparedness had affected the nation’s armed forces.²¹ In 1989, the editors of *Government Executive* magazine first used the term “hollow government,” appropriating the concept to illustrate the organizational decay that had seeped through much of the federal government during the Reagan era.²²

Today, the term is understood to describe an agency that does not have sufficient resources to efficiently and effectively perform the tasks citizens expect of it.²³ Note that “hollow government” is not the same as *small* government. An agency can be very lean but not hollow if its mission is limited and its resources are sufficient for the job. Similarly, an agency with an enormous staff still might not be able to perform its work competently if its facilities are inadequate, its operating budget is too thin, if cannot employ enough specialists to accomplish its objectives, if its computers are obsolete, or for any number of other reasons. Hollow government, in essence, is a mismatch of responsibilities and resources.

Hollow government can arise for a number of reasons which can occur singly or in combination. Sometimes it occurs because deep budget cuts or downsizing leave too little money or too few people to do the work of the agency. Sometimes new laws pile new responsibilities on the agency without any commensurate increase in funding or FTEs. Finally, sometimes there is a surge in the volume of the agency’s workload that the

²¹Mark L. Goldstein, “Hollow Government,” 21 *Government Executive* 10, October 1988, at 13.

²²Timothy B. Clark. “Editor’s Notebook,” 31 *Government Executive* 5 (May 1999), at 4.

²³*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 1 (July 25, 1991) (statement of Senator John Glenn).

agency's budget and staffing allowances cannot match.

In agencies organized into subdivisions, hollowness can afflict some parts of the organization and not others. Congress and the administration may pursue their higher priorities by dedicating revenue streams or allocating appropriations for some agency activities and not others, leading to patches of atrophy and patches of accomplishment.

If government is hollower today than in recent decades, certainly part of the problem can be attributed to attenuated staffing levels. The size of the federal government workforce has decreased for nine of the past ten years and fifteen of the past twenty years. At the end of FY 1999, the federal government employed approximately 1.82 million civilian workers—430,000 less than it employed in FY 1990.²⁴ See Figure 3. From January 1993 to December 2000, the Defense Department workforce dropped 300,000 employees—over 30 percent of its total workforce. The Department of Energy and the National Aeronautic and Space Administration both lost a quarter of their staffs, the Department of Housing and Urban Development lost 22 percent of its workers, and the Departments of Agriculture and Veterans' Affairs both shed 15 percent of their staffs.²⁵ FDA's workforce fell 3 percent over the same period, while the scope of its work exploded.²⁶

[figure redacted]

Today, there are fewer civilian employees of the federal government than at any point since 1961,²⁷ yet the population that those employees serve has risen 50 percent, from 180.67 million in 1961 to 272.69 million in

²⁴US Office of Personnel Management. *Trend of Federal Civilian On-Board Employment for Executive Branch (US Postal Service excluded) Agencies: Employment at end of Fiscal Year*, posted at: <http://www.opm.gov/feddata/exec99.htm>.

²⁵US Office of Personnel Management. *Trend of Federal Civilian On-Board Employment for Executive Branch (US Postal Service excluded) Agencies: Employment at end of Fiscal Year*, posted at: <http://www.opm.gov/feddata/exec99.htm>.

²⁶Statistic for 1990: *FDA Fiscal Year 1993 Almanac*, at 61; statistic for 1999: *FDA Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-8. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

²⁷US Office of Personnel Management. *Trend of Federal Civilian On-Board Employment for Executive Branch (US Postal Service excluded) Agencies: Employment at end of Fiscal Year*, posted at: <http://www.opm.gov/feddata/exec99.htm>.

1999.²⁸ Moreover, not only has the labor of federal employees stretched to serve more people, it has also expanded to cover new programs. For example, in 1961, the federal government did little to provide health care to the elderly or the poor; now it operates the Medicare and Medicaid programs, which serve one in four Americans.²⁹ In 1961, the federal government did not operate a federal agency designed to protect the quality of the nation's environment; now the Environmental Protection Agency regulates manufacturers, utilities, and other entities to guard against unsafe disposal of hazardous waste, air pollution, water pollution, global climate change, pesticides in food, and risks from excessively dangerous chemical substances. Medicare, Medicaid, and the Environmental Protection Agency are just three illustrations of the kinds of major federal initiatives that have been launched since 1961, yet despite the host of new federal enterprises, the federal workforce is the same size it was in 1961.³⁰

One open (and probably unanswerable) question is the extent to which technology has increased federal employees' productivity. Obviously, the greater the productivity gains, the less likely it is that downsizing the federal workforce has materially affected agencies' ability to conduct their business. There can be no doubt that innovations such as e-mail, fax machines, computerized databases, word processors, improvements in laboratory research equipment and techniques, and spreadsheets have led to substantial gains in productivity. What we cannot know is the extent to which these timesaving devices have also increased demand for services or placed new demands on the time of federal employees. As just one example, although computers have surely replaced some support staff, the agencies have hired new employees to service and maintain the computer systems. Whatever the productivity advances have been, it seems unlikely that they could have absorbed the combined effects of downsizing, population increases, new governmental initiatives, and the

²⁸US Bureau of the Census. "Historical National Population Estimates: July 1, 1900 to July 1, 1999." Posted at www.census.gov/population/estimates/nation/popclockest.txt. Revised date: June 28, 2000.

²⁹US Department of Health and Human Services. "HHS Agencies." Posted at www.hhs.gov/agencies.

³⁰US Office of Personnel Management. *Trend of Federal Civilian On-Board Employment for Executive Branch (US Postal Service excluded) Agencies: Employment at end of Fiscal Year*, posted at: <http://www.opm.gov/feddata/exec99.htm>.

expansion of agencies' existing workloads.

III. Other Agencies' Experiences with Hollow Government

It is difficult to define the point at which an agency slips from capable to hollow; like obscenity, we know hollow when we see it. But some clear-cut examples of other agencies' deterioration from penny-wise into pound-foolish may illuminate the potential harm that could result from hollowness at the Food and Drug Administration.

The Department of Health and Human Services. The Department of Health and Human Services (HHS) cut its personnel by 22 percent during the 1980s, and the effects reverberated throughout the agency. The workforce at the Health Care Financing Administration fell 20 percent at the same time that major revisions in the Medicare and Medicaid systems were implemented.³¹ By 1996, the HHS Inspector General concluded that 14 percent of all Medicare benefits paid were improper, which amounted to \$23 billion in that year alone. In 1997, the Inspector General's report stated,

[F]unding limitations have significantly constrained medical review to the extent that currently only about 3 of every 1000 providers are subject to postpayment medical review audit.... Due to limited funding, resources devoted to prepayment and postpayment review have not kept pace with the increase in claims or questionable billing practices by providers.³²

³¹Mark L. Goldstein. *America's Hollow Government: How Washington Has Failed the People*. Business One Irwin: Homewood, IL, 1992, at 73.

The Social Security Administration. The Social Security Administration also lost a great deal of personnel during the Reagan era; FTEs decreased more than 20 percent, from 80,000 to 63,000. As a result, the agency was forced to assign inexperienced and untrained workers to field telephone inquiries. An internal study discovered that staff who answered questions about Social Security benefits gave the callers a wrong answer 40 percent of the time (incorrect responses increased to 80 percent for questions regarding SSA's Supplementary Security Income). Additional studies proved that tens of thousands of poor blind, disabled, and aged persons were accidentally deprived of their SSI checks because of staff shortages.³³

The United States Coast Guard. In the late 1980s, appropriations for the Coast Guard remained stagnant or dropped, despite the fact that Coast Guard patrols played an essential role in the Reagan administration's widely announced "zero tolerance" policy for drug smuggling. The Coast Guard was forced to reduce its workforce and contend with a sharply limited budget for fuel, repairs, and spare parts. Ironically, the limited repair and fuel funds grounded planes and pilots that were supposed to be used in the administration's war on drugs, and in 1988 it even forced the Coast Guard to cut boat patrols off the coast of Florida in half.³⁴ Moreover, by 1989, the Coast Guard had atrophied to personnel levels smaller than at any time since 1972, and many of the agency's most valuable services had been cut back. Its navigation assistance was scaled back dramatically on heavily trafficked oil tanker routes, including Prince William Sound, Alaska, where the Exxon *Valdez* spilled 11 million gallons of crude oil in 1989.³⁵

The Savings and Loan Scandal. The savings and loan scandal of the 1980s and early 1990s caused the worst collapse of U.S. financial institutions since the Great Depression. Between 1986 and 1995, a total of 1,043

³³Walter Williams. "Let's Stop Strangling the Feds: Underfunding Means Sick Banks, Suspect Food, Filthy Shores." *The Washington Post*, October 14, 1990, at C5.

³⁴Mark L. Goldstein. *America's Hollow Government: How Washington Has Failed the People*. Business One Irwin: Homewood, IL, 1992, at 72.

³⁵Mark L. Goldstein. *America's Hollow Government: How Washington Has Failed the People*. Business One Irwin: Homewood, IL, 1992, at 72.

savings and loans—with assets of \$500 billion—failed. The overwhelming number of failures drained the resources of the Federal Savings and Loan Insurance Corporation, and U.S. taxpayers were left bailing out the insured depositors. By the end of the 1990s, the crisis had cost taxpayers \$124 billion.³⁶ Perhaps even more horrifying than the loss was the fact that it was avoidable, had the government employed more examiners to monitor the situation. According to banking expert Edward Kane,

As the number and scope of problem (S&L) institutions grew, the size, training and experience of the field examination force became progressively less adequate. This problem traces [in part to the Office of Management and Budget’s] unwillingness to pay high enough salaries or to establish a sufficiently attractive career ladder for examiners.³⁷

These cases illustrate a disturbing paradox: the same cutbacks that were designed to slash at government waste have in some instances actually *contributed* to waste, fraud, and abuse. The public expects competently staffed and equipped government personnel to help stem the tide of drugs into the country. Instead, the agency with the responsibility to carry out that mission was crippled under a budget so strapped for funds that its planes sat in their hangers for want of spare parts. The Medicare system projects bankruptcy in the foreseeable future, but 14 cents of every one of the billions of dollars paid into the system went for improper services. Thus, one of the collateral effects of the haste to create a smaller government has been, at least in some sectors, a considerably less efficient and productive government.

IV. Hollow Government at FDA: The 1980s.

³⁶Timothy Curry and Lynn Shibut. “The Cost of the Savings and Loan Crisis: Truth and Consequences.” *FDIC Banking Review*, December 2000, at 33. Posted at: <http://www.fdic.gov/bank/analytical/banking/2000dec/brv13n2.2.pdf>.

The Food and Drug Administration has experienced its own share of hollowing over the past decade; however, it is impossible to grasp the import of post-1990 hollowing without also understanding what happened to the agency over the course of the 1980s. During the Reagan years, FDA fell into total disarray, withstanding a long period of budget tightening, personnel downsizing, program atrophy, and even scandal.³⁸ In 1989, Dr. Samuel Thier, President of the Institutes of Medicine, described FDA as “a demoralized group, being asked to do too much with too few resources.”³⁹ Before examining the nature and effects of post-1990 hollowing, then, a review of the FDA track record during the 1980s is essential to provide adequate context.

Staffing Resources. During the 1980s, FDA staff was stretched to the breaking point. From 1980 to 1989, Congress passed 24 laws expanding FDA’s jurisdiction. During that time, the agency had to reassign 675 workers to handle the newly-enacted laws and an additional 400 workers to handle its AIDS activities.⁴⁰ Furthermore, the agency’s overall workforce fell by 691 workers, from 8,089 to 7,398.⁴¹ This suggests that only 5,623 workers remained to attend to the same responsibilities that had required 8,089 workers ten years previously. That represents a 30 percent decline in the staffing resources FDA could devote to its previous activities over the same period in which FDA-regulated industries grew by \$56 billion in *constant* dollars.⁴²

In addition to a dearth of career civil servants, the agency suffered from a lack of leadership personnel to steer the organization. From 1984 to 1990, 36 of the top 64 career management positions at FDA were vacant for stretches ranging from four months to over five years.⁴³ Thus, at a time when fewer career staff

³⁸William B. Schultz. 1992. “The Food and Drug Administration: Food, Drugs, and Medical Devices,” in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 566.

³⁹Philip J. Hilt. “Ailing Agency—The FDA and Safety: A Guardian of U.S. Health is Under Stress. *The New York Times*, December 4, 1989, at A1.

⁴⁰Philip J. Hilt. “Ailing Agency—The FDA and Safety: A Guardian of U.S. Health is Under Stress. *The New York Times*, December 4, 1989, at A1.

⁴¹*FDA Fiscal Year 1993 Almanac*, at 61.

⁴²*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 1 (July 25, 1991) (opening statement of Senator John Glenn).

⁴³Walter Williams. “Let’s Stop Strangling the Feds: Underfunding Means Sick Banks, Suspect Food, Filthy Shores.” *The*

were responsible for handling a much larger workload, very often there was no one at the helm to guide and oversee their efforts.

Scandal. The lack of oversight clearly came at a cost. In 1989, the FDA was rocked by scandal; officials in the generic drug division had accepted payoffs from generic drug firms seeking favorable treatment for their products. After the investigations, 5 of the 10 top generic drug companies were implicated for corruption, fraud, or issuing false statements. At the conclusion of the matter, there were 18 criminal guilty pleas, including the former chief of the agency's generic drugs division.⁴⁴

Budget. When controlled for inflation, the Food and Drug Administration's budget stood still during the 1980s. In 1980, the FDA's budget was \$320 million, which is equivalent to \$482 million in 1989 dollars.⁴⁵ At the decade's end, the agency's budget was \$492 million. In real dollars, the agency's budget increased just two percent over the entire decade, despite the aforementioned \$56 billion jump in FDA-regulated industries.

Activities. Unsurprisingly, the shortage of staff and funding coupled with the rise of wholly new challenges such as the AIDS virus adversely affected the performance of the agency. Enforcement grew notoriously lax, as the agency depended more and more on voluntary compliance with regulations.⁴⁶ The number of enforcement actions fell 50 percent from the end of the Carter administration to the end of the Reagan administration.⁴⁷

In addition, FDA's field resources withered significantly during the 1980s, which harmed the agency's ability to carry out its inspection responsibilities. In 1970, fully half of the agency's resources supported field ac-

Washington Post, October 14, 1990, at C5.

⁴⁴Karen Heller, David Rotman, Ronald Begley, Lyn Tattum, and Emma Chynoweth. "Pharmaceuticals: Pressure on Prices and Profits." 149 *Chemical Week* 2 (August 7, 1991), at 26.

⁴⁵FDA Center for Food Safety and Applied Nutrition. "The Story of the Laws Behind the Labels: Part III 1962 Drug Amendments." June 1981. Posted at: <http://vm.cfsan.fda.gov/~lrd/histor1b.html#toc>. 1980 statistic inflated using Bureau of Labor Statistics Inflation Calculator posted at: <http://www.bls.gov>.

⁴⁶William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 569.

⁴⁷William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 570.

tivities. By the end of the 1980s, only 38 percent of FDA's resources were devoted to field programs.⁴⁸ And while the value of FDA-regulated products increased 20 percent in constant dollars during the 1980's,⁴⁹ the number of food and drug inspections declined nearly 40 percent, from 33,000 to just under 22,000.⁵⁰

FDA also became progressively more and more handicapped at processing the growing number of premarket applications it was received each year. Industry investments in research skyrocketed, especially in the second half of the 1980s, when drug research expenditures doubled from \$4.1 billion to \$8.1 billion and medical device research increased 164 percent, from \$1.4 billion to \$3.7 billion.⁵¹

The increased corporate and academic commitment to research translated into a much larger workload for FDA, but with fewer hands to carry it out. The number of new product applications grew 82 percent from 1980 to 1989, while average approval time reached 32.5 months, compared to the legally required standard of 6 months.⁵² Medical device applications rose 185 percent from 1980 to 1989.⁵³ Instead of strengthening FDA's ability to process the new applications, however, the agency's research staff devoted to drugs actually declined 28 percent, and its medical device staff shrank 20 percent from 1985 to 1989.⁵⁴

Other important agency activities slipped during the Reagan years. In 1972, FDA had undertaken to review the claims of over-the-counter (OTC) medications. By the early 1980s, FDA-appointed scientific panels determined that two-thirds of all over-the-counter drug ingredients and claims were unsupported by scien-

⁴⁸"State of the Food and Drug Administration," speech presented to the DHHS Advisory Committee on the Food and Drug Administration by James S. Benson (Acting Commissioner of Food and Drugs), May 18, 1990.

⁴⁹*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 75 (July 25, 1991) (statement of Mark Novitch, M.D., Vice Chairman of the Board, The Upjohn Company).

⁵⁰Walter Williams. "Let's Stop Strangling the Feds: Underfunding Means Sick Banks, Suspect Food, Filthy Shores." *The Washington Post*, October 14, 1990, at C5.

⁵¹*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 78 (July 25, 1991) (statement of Mark Novitch, M.D., Vice Chairman of the Board, The Upjohn Company).

⁵²Karen Heller, David Rotman, Ronald Begley, Lyn Tattum, and Emma Chynoweth. "Pharmaceuticals: Pressure on Prices and Profits." 149 *Chemical Week* 2 (August 7, 1991), at 26.

⁵³"State of the Food and Drug Administration," speech presented to the DHHS Advisory Committee on the Food and Drug Administration by James S. Benson (Acting Commissioner of Food and Drugs), May 18, 1990.

⁵⁴*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 79 (July 25, 1991) (statement of Mark Novitch, M.D., Vice Chairman of the Board, The Upjohn Company).

tific evidence. Despite this finding, because of cutbacks during the Reagan administration, the number of employees reviewing over-the-counter medications fell by almost half. By the end of the decade, the agency had finished reviewing just 20 percent of OTC ingredients. As late as 1992, more than half of the OTC ingredient categories were still awaiting final decisions.⁵⁵

The agency's rulemaking process nearly ground to a halt in the 1980s. The Medical Device Amendments were enacted in 1976, and it took FDA eight years to issue the regulations mandated by the law. As of 1992, the agency had not issued regulations under the Orphan Drug Act of 1983, or the Drug Competition and Patent Term Restoration Act of 1984.⁵⁶ In 1991, the House Subcommittee on Health and the Environment asked FDA to produce a list of pending regulations, and its ability to track its own regulations was in such a state of disorganization that it was unable to do so. When FDA finally released the list, it revealed that the agency's pending regulations had been under consideration for an average of nine years. The regulations designated as important took an average of five years to promulgate. Two regulations had been pending for 29 years each.⁵⁷

Facilities and Equipment. With the increased workload and a shrinking staff, FDA was unable to free enough resources to support decent investments in facilities and equipment. By 1990, the results were obvious: a federal advisory committee examining the condition of the Food and Drug Administration variously described the administration's facilities as "obsolete," "technologically inadequate," and "abysmal."⁵⁸ Of the nine FDA laboratories, four were rated as "unacceptable," and at times high heat and humidity would shut off sensitive equipment, wrecking scientists' efforts to test food products.⁵⁹ Overcrowding became another

⁵⁵William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 572.

⁵⁶William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 572.

⁵⁷William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 572.

⁵⁸*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 2 (July 25, 1991) (opening statement of Senator John Glenn).

⁵⁹Walter Williams. "Let's Stop Strangling the Feds: Underfunding Means Sick Banks, Suspect Food, Filthy Shores." *The Washington Post*, October 14, 1990, at C5.

serious problem. For example, even senior scientists with the Center for Veterinary Medicine worked in trailer homes, while the adjacent laboratories were housed in 1930s-era barns.⁶⁰

Equipment had deteriorated so badly that scientists were spending increasing amounts of time troubleshooting and fixing equipment instead of actually conducting their research. On some projects, scientists were forced to customize equipment from available parts in order to accomplish specific jobs. Other times, the agency was forced to borrow equipment from industry in order to carry out its work.⁶¹

In addition to the obvious productivity impediments that poor facilities and equipment created, they also harmed the agency's morale and made it harder for FDA to compete with academia and the private sector when attempting to attract well-qualified employees, especially when FDA paid scientists far less than academia.⁶²

Summary. At the close of the 1980s, it was apparent that FDA faced an organizational crisis. Its staff, its facilities, its equipment, and its reputation were all in the midst of a downhill slide. The agency's acting Commissioner James Benson characterized the agency's condition as follows:

⁶⁰ "State of the Food and Drug Administration," speech presented to the DHHS Advisory Committee on the Food and Drug Administration by James S. Benson (Acting Commissioner of Food and Drugs), May 18, 1990.

⁶¹ "State of the Food and Drug Administration," speech presented to the DHHS Advisory Committee on the Food and Drug Administration by James S. Benson (Acting Commissioner of Food and Drugs), May 18, 1990.

⁶² Walter Williams. "Let's Stop Strangling the Feds: Underfunding Means Sick Banks, Suspect Food, Filthy Shores." *The Washington Post*, October 14, 1990, at C5.

Since 1976, Congress has assigned FDA vast responsibilities under several new laws, requiring major initiatives in areas such as medical devices, generic drugs, drug diversion, orphan drugs, pesticides, AIDS and anabolic steroids. The cumulative effect has forced FDA to “withdraw” more assets than it has in its resource bank. In effect, we are “overdrawn” on virtually all accounts. FDA managers have been forced to cannibalize core functions and other programs to accommodate these new legislated activities.⁶³

Soon after, a Department of Health and Human Services Advisory Committee echoed Benson’s conclusion, stating, “It is glaringly apparent that the FDA cannot now execute all of its statutory responsibilities within the limitations of available resources.”⁶⁴ In short, at the beginning of the 1990s, FDA was an agency with virtually no ability to absorb more organizational hits without shattering.

V. Hollow Government at FDA, 1990 to the Present.

FDA officials opened the decade of the 1990s determined to take stock of the organization’s situation. In March 1990, U.S. Secretary of Health and Human Services Louis W. Sullivan named an advisory committee to examine FDA’s mission, priorities, structure, budget, and workforce.⁶⁵

After the commission completed its assessment, the panel’s chairman, Charles C. Edwards, testified before a

⁶⁴ *Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 2 (July 25, 1991) (opening statement of Senator John Glenn).

⁶⁵ Advisory Committee on FDA Final Report, HHS Press Release (May 15, 1991).

Senate committee that the FDA was “at the breaking point;” further, that “without the fundamental changes we call for in the report, the risk of impending public health catastrophe will only grow.”⁶⁶ Upon reviewing the report, Senator Ted Kennedy, the Chairman of the Senate Labor and Human Resources Committee, concluded,

The agency is overextended, underfunded and whip-sore by multiple layers of bureaucratic review and restraint. Each time confidence in the agency is eroded, and FDA staff becomes demoralized, the nation moves closer to a real possibility of a major health disaster. Will it be in the food supply, in prescription drugs, in the blood banks? No one can predict. But what we can say reading this report is that we are living too close to the edge.⁶⁷

Despite all the concern, throughout the decade, FDA’s resources continued to be stretched beyond all limits. Staffing Resources. Between 1990 and 1999, FDA’s workforce grew from 7,814 to 8,910 FTEs.⁶⁸ Most of the growth came in the early 1990s, as the staff grew 8 percent in 1991 and 6 percent in 1992. For much of the rest of the decade, personnel levels stagnated.⁶⁹ See Figure 4.

The allocation of employees within FDA also remained relatively fixed during the 1990s, suggesting that the agency’s relative priorities did not shift significantly over the past ten years. For example, in 1992, the Center for Devices and Radiological Health constituted 10.9 percent of FDA’s workforce; now it comprises 11.1 percent of the agency’s workforce. Similarly, the Center for Veterinary Medicine was 3.2 percent of the agency’s overall staff in Fiscal Year 1992 and 3.3 percent in Fiscal Year 2001.⁷⁰

⁶⁶Karen Heller, David Rotman, Ronald Begley, Lyn Tattum, and Emma Chynoweth. “Pharmaceuticals: Pressure on Prices and Profits.” 149 *Chemical Week* 2 (August 7, 1991), at 26.

⁶⁸1990 statistic: *FDA Fiscal Year 1993 Almanac* at 63. 1999 statistic: 2001 FDA All Purpose Table—Total Program Level.

⁶⁹1990-1993 statistics: *FDA Fiscal Year 1993 Almanac* at 63. 1994 statistic: *FDA Fiscal Year 1995 Almanac* at 19. 1995 statistic: *FDA Fiscal Year 1996 Almanac* at 17. 1996 statistic: *FDA Fiscal Year 1997 Almanac* at 10. 1997 statistic: 1999 FDA All Purpose Table—Total Program Level. 1998 statistic: 2000 FDA All Purpose Table—Total Program Level. 1999 statistic: 2001 FDA All Purpose Table—Total Program Level.

⁷⁰1990-1993 statistics: *FDA Fiscal Year 1993 Almanac* at 61. 1994 statistic: *FDA Fiscal Year 1995 Almanac* at 19. 1995 statistic: *FDA Fiscal Year 1996 Almanac* at 17. 1996 statistic: *FDA Fiscal Year 1997 Almanac* at 10. 1997 statistic: 1999 FDA All Purpose Table—Total Program Level. 1998 statistic: 2000 FDA All Purpose Table—Total Program Level. 1999

[figure redacted]

The two notable changes that did occur took place in the areas of field resources and human drugs. The proportion of field staff dropped 3 percent over the course of the decade, and the proportion of Center for Drug Evaluation and Research employees grew 4.5 percent. Today, the agency's largest components are its field arm (the Office of Regulatory Affairs) at 35 percent of the total staff, and the Center for Drug Evaluation and Research at 21 percent.⁷¹ See Figure 5.

[figure redacted]

Budget. When attempting to quantify FDA's workload and resources, no measure is more difficult to pin down than the agency's budget. Especially after the introduction of industry-paid user fees, FDA's budget can be calculated in a seemingly endless variety of ways. For instance, some descriptions of the budget classify the various forms of expenditures into salaries and expenses (S&E), S&E plus rent and rent-related activities, or S&E, rents, and buildings and facilities (which is also known as the total program level). Alternatively, some accounts focus on user fees, classifying the budget in terms of budget authority (the amount of funds that Congress and the President make available to the agency) and total program level (the budget authority plus user fees). The budget also often includes classification for non-contingent and contingent funding, which tags the agency's resource level to the occurrence (or non-occurrence) of a particular event, such as adoption of a new user fee.

statistic: 2001 FDA All Purpose Table—Total Program Level.

⁷¹1990-1993 statistics: *FDA Fiscal Year 1993 Almanac* at 61. 1994 statistic: *FDA Fiscal Year 1995 Almanac* at 19. 1995 statistic: *FDA Fiscal Year 1996 Almanac* at 17. 1996 statistic: *FDA Fiscal Year 1997 Almanac* at 10. 1997 statistic: 1999 FDA All Purpose Table—Total Program Level. 1998 statistic: 2000 FDA All Purpose Table—Total Program Level. 1999 statistic: 2001 FDA All Purpose Table—Total Program Level.

Another potential source of variation rests in the distinctions between budget authority, budget obligation, and budget outlays. As mentioned above, budget authority is the legal basis upon which agencies are allowed to commit funds to its activities. Budget obligations occur when the agency commits money to a certain purpose. The monies which the agency actually spends are called budget outlays. None of the three measures are exactly equal in most years. For instance, if an agency orders equipment in one year and pays for it in the next year, it has transformed congressional budget authority into a budget obligation in the first year, but it does not create an outlay until the following year when it actually transfers the money to the vendor.⁷²

Furthermore, user fees are estimated during the budget planning process, so if demand for the applicable services is not exactly what the agency forecast, its revenues from user fees will vary from FDA's budget estimates. In addition, in many years, the originally-adopted budget must undergo a rescission process because the government has appropriated too much money.

In short, especially after the establishment of user fees, FDA budgets are moving targets that can be defined in dozens of ways, and which are revised for years following the actual expenditures. To illustrate the complexity of tracking the agency's budget, Figure 6 surveys seven documents that define FDA's FY 1995 budget and shows the wide range of results, even among numbers that ostensibly measure the budget in the same way. For example, the FY 1995 "Annual Budget for S&E with User Fees" was listed as \$893 million in a 1997 FDA document and \$904 million in a 1995 document. FY 1995 "Total Program Level" was assessed at \$904 million in a 1995 FDA document, while FY 1995 "Program Level Total" was calculated at \$948 million in a 1996 FDA document. Thus, while comparisons across years are unavoidable in this paper, it should be understood that the budget figures used are more fraught with uncertainty than other quantifiable measures of the agency's resources and output.

⁷²Congressional Research Service, "A Brief Introduction to the Federal Budget Process," Congressional Research Service Report to Congress (October 20, 1997) 96-912 GOV, posted at: <http://www.cnire.org/nle/info-6.html>.

Figure 6.

Various Measures of FDA's FY 1995 Budget

Budget Measurement	FY95 Budget (in millions)	Source
Actual S&E	\$818	<i>The Budget of the United States Government Fiscal Year 1997: Appendix at 471.</i>
Annual Budget for S&E without User Fees	\$818	<i>FDA Almanac Fiscal Year 1995 at 16, FDA Almanac Fiscal Year 1996 at 16, FDA Almanac Fiscal Year 1997 at 9.</i>

Actual Net Out- lays	\$860	<i>The Bud- get of the United States Gov- ern- ment Fis- cal Year 1997: Ap- pendix at 471.</i>
Actual BA	\$869	<i>FDA Almanac Fiscal Year 1996 at 15.</i>
Net BA	\$882	<i>The Budget of the United States Government Fiscal Year 1997: Appendix at 471</i>
Annual Budget for S&E with User Fees	\$892	<i>FDA Almanac Fiscal Year 1996 at 16.</i>
Total Activity	\$892	<i>FDA Almanac Fiscal Year 1996 at 15.</i>
Annual Budget for S&E with User Fees	\$893	<i>FDA Almanac Fiscal Year 1997 at 9.</i>
Annual Budget for S&E with User Fees	\$904	<i>FDA Almanac Fiscal Year 1995 at 16.</i>
Total Program Level	\$904	<i>FDA Almanac Fiscal Year 1995 at 16.</i>
Program Level Total	\$948	<i>FDA Almanac Fiscal Year 1996 at 15.</i>
Total Obligations	\$961	<i>The Budget of the United States Government Fiscal Year 1997: Appendix at 471.</i>
Gross BA	\$973	<i>The Budget of the United States Government Fiscal Year 1997: Appendix at 471.</i>

Figure 7 shows the range of divergence among ten different budget measurements. This paper will use Salaries and Expenses with User Fees as its yardstick for comparison over the years. Salaries comprise over

60 percent of FDA's annual budget,⁷³ and S&E factors out capital expenses, which can fluctuate significantly without greatly affecting the agency's output.

[figure redacted]

Despite explosive growth in the industries which FDA is expected to police, the agency's budget has seen only modest increases in the past decade and is still miniscule in comparison to the regulated industries. In fact, as of 1995, the entire FDA budget was roughly one-half of one percent of R&D spending on FDA-regulated products.⁷⁴

[figure redacted]

After accounting for inflation, FDA's S&E budget has increased just 28 percent since FY 1990, from \$565 million⁷⁵ (which equals \$744 million in 2000 dollars⁷⁶) to \$950 in FY 2000.⁷⁷ See Figure 8. The growth slowed as the decade wore on; from 1995 to the present, salaries and expenses rose only 16 percent in real dollars⁷⁸ and 2.8 percent in constant dollars.⁷⁹

This leads to an unavoidable collision between the expectations of FDA and its ability to respond within

⁷³FDA Fiscal Year 2002 Congressional Budget Request at 158, posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/part2.pdf>.

⁷⁴*FDA Fiscal Year 1995 Almanac*, at 16.

⁷⁵FDA 1999 Congressional Budget Request, posted at: <http://www.fda.gov/oc/oms/ofm/budget99cj.htm>

⁷⁶Statistic inflated using Bureau of Labor Statistics Inflation Calculator posted at: www.bls.gov.

⁷⁷Budget of the United States Government, Fiscal Year 2002, at 436. Posted at: <http://w3.access.gpo.gov/usbudget/fy2001/pdf/hhs.pdf>. <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf>.

⁷⁸1995 statistic: *The Budget of the United States Government Fiscal Year 1997: Appendix* at 471. 2000 statistic: Budget of the United States Government, Fiscal Year 2002, at 436. Posted at: <http://w3.access.gpo.gov/usbudget/fy2001/pdf/hhs.pdf>.

⁷⁹Statistic inflated using Bureau of Labor Statistics Inflation Calculator posted at: www.bls.gov.

budgetary constraints. When FDA attempts to manage a workload which has expanded immensely since 1995 on a budget that has increased less than 3 percent, either the quantity or the quality of its monitoring will have to be reduced correspondingly (unless there were significant inefficiencies in the agency that could be corrected quickly, which is highly unlikely). Thus, hollow government is created or exacerbated if it already existed.

Activities. The modest increases in FDA's budget may appear generous compared to the funding cuts and reductions-in-force that many other agencies experienced during the 1990s. But the slight gains that FDA made did not come close to matching the skyrocketing growth in the industries FDA is required to regulate. Today, those industries add \$2 billion to their domestic research and development (R&D) budgets every year. In 1998, drug companies spent \$20 billion per year on R&D, which is triple the amount of expenditures from just ten years previously. Furthermore, research budgets at government entities such as the National Institutes of Health are on the rise.⁸⁰ The results of the heightened commitment to R&D have been impressive from a scientific standpoint but have also increased the burdens on FDA. For example:

- Investigational new drug applications for biologics rose from 379 in FY 1990 to 674 in FY 2000—a 78 percent increase.⁸¹

- The number of New Drug Applications approved by the Center for Drug Evaluation and Research increased 42 percent between FY 1990 and FY 2000, from 69 to 98.⁸²

- Between FY 1990 and FY 2000, the number of abbreviated new drug approvals rose 217 percent, from 73 to 232.⁸³

- New Animal Drug Applications rose 43 percent from FY 1990 to FY 2000, from 898 to 1286.⁸⁴

- The number of FDA-regulated advertisements for prescription drugs rose over 400 percent from 1993 to 2000.⁸⁵

As FDA's resources stretch thinner and thinner, some of its basic responsibilities have been neglected. For example, the agency's field work has dwindled significantly over the past decade. Today, 1,100 inspectors and investigators in the Office of Regulatory Affairs are responsible for covering almost 95,000 FDA-regulated

⁸⁰FDA Plan for Statutory Compliance, 64 Fed. Reg. 65,005 (1998).

businesses.⁸⁶ The number of enforcement actions, which is tied directly to the agency's inspection activities, has dropped precipitously over the past decade. In 1991, for example, the agency carried out 168 seizures; in 2000, it ordered only 25—a drop of 85 percent.⁸⁷ The number of injunctions demanded by the agency fell by more than half, from 21 in 1991 to 8 in 1999.⁸⁸ See Figure 9.

[figure redacted]

The number of regulatory warning letters and recalls increased markedly during the same period. See Figure 10. This can also be understood as a symptom of an overwhelmed inspection operation. Recalls typically occur when a contaminated or dangerous product has already reached store shelves. Inspections are supposed to prevent contaminated materials from reaching the shelves in the first place. Thus, the 30 percent surge in recalls over the past ten years may be partially attributable to FDA's diminishing ability to deter food safety violations or spot them before they are unleashed on the public.

[figure redacted]

Summary. There is growing evidence that the Food and Drug Administration is in severe organizational distress; its resources are not keeping pace with its workload. Staff members assigned to review premarket

⁸⁶*FDA Annual Report: Fiscal Year 1998*, July 1999, at 4. Posted at: www.fda.gov/oc/oms/ofm/accounting/98report.pdf.

⁸⁷1991 statistic: *FDA Fiscal Year 1993 Almanac*, at 23. 1999 statistic: FDA, "FDA Takes Action to Enforce the Law," *FDA Consumer* (May/June 2000). Posted at: www.fda.gov/fdac/features/2000/300_law.html.

⁸⁸1991 statistic: *FDA Fiscal Year 1993 Almanac*, at 23. 1999 statistic: FDA, "FDA Takes Action to Enforce the Law," *FDA Consumer* (May/June 2000). Posted at: www.fda.gov/fdac/features/2000/300_law.html.

applications are under tremendous pressure to approve drugs easily and quickly.⁸⁹ Inspections and enforcement actions are lagging. This means that, at the same time the agency is becoming less rigorous about the products it allows into enter the marketplace, the products that are actually in the marketplace are being monitored less diligently.

Instead of giving FDA the resources to do the work that the American public expects it to do or, alternatively, making explicit choices about how to pare back the expectations of the agency, Congress and the President have allowed the agency to hollow out, spreading its resources like an ever-thinner veneer across the vast expanse of territory under its charge.

In 1990, Acting FDA Commissioner James Benson reflected on the situation of the agency and observed,

[U]ncontrolled and unrealistic expectations place a heavy burden on the timeliness, efficiency, quality and thoroughness with which we do our job. The plain truth is that over the last 15 years, FDA has been overwhelmed with new organizational and statutory responsibilities.... Rather than indexing resource levels to our program responsibilities and following the “pay as you go” principle, policy-makers have forced FDA to absorb costly new programs without commensurate resource increases to implement them.⁹⁰

VI. Biologics

FDA’s jurisdiction consists of five major areas: biologics, food, animal feed and drugs, medical devices and radiological health, and human drugs. Each of these areas is supported by a headquarters operation where premarket testing and research take place, and field offices throughout the country which serve under

⁸⁹See, for example, David Willman, “How a New Policy Led to Seven Deadly Drugs.” *Los Angeles Times* (December 20, 2000), at A1.

the agency's Office of Regulatory Affairs. The agency also supports several smaller programs, such as the National Center for Toxicological Research, the Office of Tobacco, and the Office of the Commissioner, but this paper will proceed with a closer examination only of hollowing symptoms within the FDA's main centers.

The Food and Drug Administration's Center for Biologics Evaluation and Research is charged with overseeing the safety, effectiveness, and timely delivery of biological products, such as blood, tissue, allergenics, vaccines, and biological therapeutics.⁹¹ This is a rapidly developing field of medicine, and CBER's jurisdiction has expanded over the past several years to include such responsibilities as banked human tissues, somatic cell therapy, gene therapy, and research on bioterrorism.⁹² A growing share of CBER's work is in cooperation with the biotech industry, which today encompasses approximately 1,300 small- and middle-sized biotech firms employing about 100,000 skilled workers. The industry devotes \$8 billion on research and development each year, which has fed a significant growth in the demand for FDA review of new products.

Activities. Before a biologic product can be marketed in the United States, CBER must license both the product and the establishment that intends to manufacture it. The main categories of premarket applications for biologics are Investigational New Drug Applications (INDs), Investigational New Drug Exemptions (IDEs), standard original New Drug Applications, Product License Applications, and Biologic License Applications.

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INDs and IDEs are requests for FDA's permission to administer a product to a patient prior to clinical trials.

⁹¹Center for Biologics Evaluation and Research. "About Us," posted at: www.fda.gov/cber/about.htm.

⁹²Center for Biologics Evaluation and Research. "Frequently Asked Questions," posted at: www.fda.gov/cber/faq.htm.

⁹³*FDA Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-27. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

From FY 1990 to FY 2000, total INDs and IDEs have increased 190 percent, from 379 to 722.⁹⁴ Similarly, since 1990, the number of IND amendments (which are requests to alter the terms of an existing license) rose 150 percent, and the number of active INDs climbed 170 percent.⁹⁵ See Figure 11. The biotech industry is responsible for a great deal of the growth in demand for CBER's premarket reviews: the number of biotech INDs increased from 5 in FY1980 to 327 in FY1998 to 429 in FY1999 (which represents a 30 percent increase from 1998 to 1999 alone).⁹⁶

[figure redacted]

Other indexes of CBER's activities also demonstrate striking growth. The average number of applications for biological products licensing has risen dramatically since the beginning of the decade, from an average of 54 per year during 1990-1992 to 75 per year from 1998-2000 (see Figures 12 and 13).⁹⁷ The number of supplements to biological product applications has increased 270 percent from 1990 to 2000.⁹⁸

[figure redacted]

[figure redacted]

⁹⁴1990 statistic: *FDA Fiscal Year 1993 Almanac*, at 37. 2000 statistic: Center for Biologics Evaluation and Research, "Report to the Biologics Community," at 30. Posted at: www.fda.gov/cber/inside/biolrpt.pdf.

⁹⁵1990 statistic: *FDA Fiscal Year 1993 Almanac*, at 37. 2000 statistic: Center for Biologics Evaluation and Research, "Report to the Biologics Community," at 30. Posted at: www.fda.gov/cber/inside/biolrpt.pdf.

⁹⁶*FDA Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-27. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

⁹⁷1990 statistic: *FDA Fiscal Year 1993 Almanac*, at 37. 2000 statistic: Center for Biologics Evaluation and Research, "Report to the Biologics Community," at 30. Posted at: www.fda.gov/cber/inside/biolrpt.pdf.

⁹⁸1990 statistic: *FDA Fiscal Year 1993 Almanac*, at 37. 2000 statistic: Center for Biologics Evaluation and Research, "Report to the Biologics Community," at 30. Posted at: www.fda.gov/cber/inside/biolrpt.pdf.

CBER is also responsible for policing the content of biologics advertisement, and the volume of its reviews grew nearly 300 percent in just six years, from 1995 to 2000. See Figure 14.

[figure redacted]

As other demands on the agency's time and resources have increased, CBER's research activities have been substantially curtailed over the past several years. Historically, CBER has spent more money than the other centers at FDA on original research beyond its core activities, such as reviewing and licensing biological products. But in 1997, the pharmaceutical companies paying user fees persuaded Congress to prohibit the expenditure of those fees for research.⁹⁹ Consequently, CBER's laboratory budget and its research budget both dropped by half in just four years, from 1994 to 1998.¹⁰⁰ See Figure 15.

The Center's move away from conducting original research was sharply criticized by a 27-member panel of outside experts who conducted an extensive review of science at FDA. In the words of the group's report, the committee's activities extended beyond its assigned task in order to "address the committee's unanimous concern that inadequate funding... for laboratory research within CBER would risk potential damage not only the health of the population of the United States but also the health of our economy."¹⁰¹ Nonetheless, the Center's growing responsibilities together and the user fee prohibition together have dramatically reduced the Center's once highly esteemed research enterprise.

⁹⁹Eliot Marshall, "Panel Issues Plea to Boost FDA Research." 280 *Science* 5368 (May 29, 1998), at 1341.

¹⁰⁰Stakeholder slides from CBER presentation.

¹⁰¹Quoted in Eliot Marshall, "Panel Issues Plea to Boost FDA Research." 280 *Science* 5368 (May 29, 1998), at 1341.

[figure redacted]

Staffing. Meanwhile, as program activity continued on the upswing and research was waning, the agency staff devoted to biologics actually *decreased* over the past four years. FDA's biologics staff is composed of two different arms: its headquarters staff at the Center for Biologics Evaluation and Research and the field staff devoted to biologics within the Office of Regulatory Affairs. Together, the two groups of employees form what is known as the Program Level workforce. Last year, CBER employed 780 FTEs at its headquarters, and another 211 FTEs employed by the Office of Regulatory Affairs handled CBER's field activities, for a total program level staff of 991.¹⁰² This represents a program level decline of about 80 FTEs since 1997, and the reduction came exclusively from the headquarters operation. The Center's staff declined about 4 percent per year from 1997 to 1999 and is now smaller than at any time since 1993.¹⁰³ See Figure 16.

[figure redacted]

Biologics positions are funded in one of two ways. Some FTEs are supported through the Salaries and Expenses portion of the program's federal budget authority. Others are funded through industry user fees. Beginning in the early 1990s, FDA-regulated industries have paid user fees which the agency has used to bolster the staff available to conduct regulatory reviews. As the number of PDUFA-funded FTEs has increased, however, the number of FTEs supported by normal budget authority has declined, eroding 40 to 50 of the 200 or so new positions backed by industry dollars. See Figure 15. In short, the evidence suggests that, although the expectations of CBER and the biologics field operation have increased substantially in

¹⁰²Food and Drug Administration Fiscal Year 2002 Budget Request, April 2001, at 85. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁰³FDA Chief Financial Officer's Annual Report: FY 1999, April 2000, at I-25. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

the past decade, there has been no commensurate increase in the number of employees charged with meeting those expectations.

Budget. Last year, the budget of the Center and its affiliated field efforts was \$141 million, which represented just an 8 percent increase over the past five years, without accounting for inflation.¹⁰⁴ Taking inflation into account, the budget actually fell four percent.¹⁰⁵ For the past four years, budget authority has accounted for between 75 and 78 percent of the of the total funding for biologics, while industry user fees contribute the balance of program level funding.¹⁰⁶ See Figure 17.

As the previous section detailed, the workload of the agency has grown in volume and complexity in recent years, while the budget has remained stagnant. Thus, the agency is now required to attempt more work using less money and fewer FTEs. Unless the agency discovered a way to increase productivity significantly (and instantly), it seems highly unlikely that the agency could be performing at the same standards of quality that it did while better funded and staffed.

[figure redacted]

Summary. The evidence could hardly be clearer that the workload of CBER and the biologics field staff is increasing faster than the budget and staff can accommodate. FDA's biologics program is entrusted with

¹⁰⁴1995 statistic: *FDA Almanac, FY 1996* at 15. 2000 statistic: FDA FY 2002 Congressional Budget Request All Purpose Table—Total Program Level. Posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf.

¹⁰⁵1995 statistic inflated using Bureau of Labor Statistics Inflation Calculator, posted at: www.bls.gov.

¹⁰⁶1997 statistic: FDA FY 2000 Congressional Budget Request User Fee History. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/net171.htm>.

1998 statistic: FDA FY 2000 Congressional Budget Request All Purpose Table—Total Budget Authority. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/netapt26.htm>.

1999 statistic: FDA FY 2001 Congressional Budget Request All Purpose Table—Total Budget Authority. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2001/tables/APTcharts4net.htm>.

2000 statistic: FDA FY 2002 Congressional Budget Request All Purpose Table—Total Budget Authority. Posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/CurrentLawBA.PDF.

responsibilities as grave as ensuring the safety of the nation's blood supply, the vaccines we administer to children, and new gene therapies. All of these treatments can be lifesaving if properly utilized but carry a risk of death if mishandled. FDA has been forced to stretch this important program to the breaking point, utilizing less scientists, fewer inspections, stagnant budgets, and less research to police an exploding array of biological products and establishments, inviting a public health catastrophe.

VII. Food and Cosmetics.

The jurisdiction of FDA's food and cosmetics program is enormous and growing faster than the agency can keep up. As noted above, U.S. residents spend 25 cents of every consumer dollar on products which the Food and Drug Administration regulates, and three-quarters of this amount is spent on food.¹⁰⁷ Together, the FDA's Center for Food Safety and Applied Nutrition and the associated field staff in the Office of Regulatory Affairs monitor foods with an annual retail value of \$430 billion¹⁰⁸ and cosmetics with an annual retail value of \$15 billion.¹⁰⁹

The food and cosmetics program supports a number of endeavors ranging from research and premarket reviews to postmarket surveillance. US food processors spend \$1.4 billion on R&D each year, creating between 10,000 and 15,000 new products.¹¹⁰ Some of those products utilize new food additives, which require premarket approval. Its inspection and investigation efforts are even more daunting: the program is

¹⁰⁷US FDA, Center for Food Safety and Applied Nutrition. "Center for Food Safety and Applied Nutrition Overview." Posted at: <http://vm.cfsan.fda.gov/~lrd/cfsan4.html>.

¹⁰⁸FDA Chief Financial Officer's Annual Report: FY 1999, April 2000, at I-12. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹⁰⁹US FDA, Center for Food Safety and Applied Nutrition. "Center for Food Safety and Applied Nutrition Overview." Posted at: <http://vm.cfsan.fda.gov/~lrd/cfsan4.html>.

¹¹⁰FDA Chief Financial Officer's Annual Report: FY 1999, April 2000, at I-12. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

responsible for monitoring 57,000 food establishments¹¹¹ and 3,500 cosmetic companies,¹¹² and it supplies states and localities with model codes, technical assistance, and other guidance to assist their regulation of another 600,000 restaurants and 235,000 supermarkets across the country.¹¹³

Premarket Applications. In the mid-1990s, the Center for Food Safety and Applied Nutrition undertook a variety of measures to improve the quality and speed of its various petition review processes. It devoted more resources to its computer systems, expanding its capacity for processing electronic information. It also reassigned scientists from other program areas within FDA to study food applications. Finally, the Center greatly enhanced the guidance services it provides to applicants, which has led to better submissions to the agency.¹¹⁴

According to FDA, the new procedures helped them speed reviews and ease the backlog of petition applications. In mid-1995, 295 petitions, including food and color additive petitions, “Generally-Recognized-As-Safe” (GRAS) petitions, and citizen petitions, awaited review. Just a year and a half later, at the end of 1996, the Center had received 82 more petitions, but the backlog was cut to 235 petitions.¹¹⁵ Between 1993 and 1997, the median time elapsing between the Center’s receipt of an application and a final decision fell from 37 months to 27 months.¹¹⁶

¹¹¹Greg Winter, “Contaminated Food Makes Millions Ill Despite Advances,” *The New York Times* (March 18, 2001), at A1.

¹¹²US FDA, Center for Food Safety and Applied Nutrition. “Center for Food Safety and Applied Nutrition Overview.” Posted at: <http://vm.cfsan.fda.gov/~lrd/cfsan4.html>.

¹¹³US FDA, Center for Food Safety and Applied Nutrition. “Center for Food Safety and Applied Nutrition Overview.” Posted at: <http://vm.cfsan.fda.gov/~lrd/cfsan4.html>.

¹¹⁴*Hearing Before the Committee on Labor and Human Resources, United States Senate*, 105th Cong. (March 19, 1997) (statement of Michael A. Friedman, M.D., Deputy Commissioner for Operations, Food and Drug Administration). Posted at: <http://www.fda.gov/ola/1997/319.html>.

¹¹⁵*Hearing Before the Committee on Labor and Human Resources, United States Senate*, 105th Cong. (March 19, 1997) (statement of Michael A. Friedman, M.D., Deputy Commissioner for Operations, Food and Drug Administration). Posted at: <http://www.fda.gov/ola/1997/319.html>.

¹¹⁶*Hearing Before the Committee on Labor and Human Resources, United States Senate*, 105th Cong. (March 19, 1997) (statement of Michael A. Friedman, M.D., Deputy Commissioner for Operations, Food and Drug Administration). Posted at:

A broader examination of the petition data reveals more mixed results. For instance, while it is true that the agency disposed of dozens of backlogged petitions in 1995 and 1996, the total number of food additive petitions under review remained essentially unchanged over a longer period of time. Even at the end of 1996, the backlog had shrunk only 7 percent below 1990 levels and was virtually the same as the totals left at the end of Fiscal Years 1994 and 1995. Moreover, the slow response was not attributable to a long-term upsurge in the number of petitions that the Center was receiving: food additive application submissions fell almost 36 percent from 1990 to 1996, yet the accumulation of petitions awaiting review barely receded. In fact, the number of petitions awaiting action for more than 180 days actually increased 62 percent from 1990 to 1996. See Figure 18.

[figure redacted]

In the years since 1996, FDA has ceased publishing in any of its budget or Government Performance and Review Act reports the number of food additive applications receipts it has received. Instead, the documents state only the percentages of applications the Center approved within 360 days of receipt and the percentage of overdue applications under active review. In 1999, the most recent year for which data are available, 54 percent of the petitions were approved on time. Among the current group of overdue applications, only 42 percent are even under active review.¹¹⁷

Field Activities. Perhaps more than in any other area of FDA's activities, the food program's field operation reveals symptoms of hollow government. As noted above, FDA's food program regulates \$430 billion in

<http://www.fda.gov/ola/1997/319.html>.

¹¹⁷Food and Drug Administration FY 2001 Congressional Budget Request. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2001/foods.htm>.

goods,¹¹⁸ 4.1 million food imports,¹¹⁹ and 57,000 manufacturing plants.¹²⁰ Yet the program's *entire* nationwide field staff (including *all* employees, not just investigators and inspectors) consists of just 1,556 FTEs.¹²¹ While the United States Department of Agriculture employs 6,000 inspectors to test meat and poultry,¹²² FDA retains a staff less than one-tenth that size to test all other foods—despite the fact that the General Accounting Office has calculated that 85 percent of all cases of food poisoning come from foods regulated by FDA, not USDA.¹²³

Because of a shrinking staff, the number of food safety inspections has fallen precipitously, now amounting to just a third of what it was in the 1980s.¹²⁴ Today, about 400 FDA inspectors are responsible for policing 57,000 food manufacturing plants around the country; proportionally, that means that there is only one inspector for every 150 establishments. FDA is under no statutory obligation to visit the plants regularly, and the inspectors are so overwhelmed with work that each plant is inspected about once every eight years.¹²⁵ See Figure 19.

[figure redacted]

Imported foods have become another serious problem for the agency. Over the past decade, the number of different items that grocery stores stock has doubled, with a large share of the increase coming from imported

¹¹⁸FDA *Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-12. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹¹⁹Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹²⁰FDA *Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-12. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹²¹FDA *All Purpose Table—Current Law Program Level 2002*, at <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf>.

¹²²United States Department of Agriculture Food Safety and Inspection Service, "Human Resources Division: Food Inspectors." Posted at: <http://www.fsis.usda.gov/OM/HRD/emply.career/fi.htm>

¹²³Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹²⁴Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹²⁵Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

products. In the past four years alone, the number of foreign food items consumed in the United States rose 50 percent, from 2.7 million items in 1997 to 4.1 million items in 2000. In that time, the total number of inspectors examining food imports nationwide only increased from 110 to 113, which means that, on a proportional basis, each inspector is now responsible for covering more than 36,000 imports per year.¹²⁶ As a result, FDA's coverage of imported shipments has plummeted. From 1992 to 1997, the proportion of imports inspected fell 80 percent, from 8 percent in 1992 to 1.7 percent in 1997.¹²⁷ Today, FDA inspects fewer than 1 percent of all imported foods.¹²⁸ Many of the foods come from countries in which food processing and regulatory systems are not as advanced as those found in the United States,¹²⁹ and 40 percent of the imported foods which FDA actually inspects are rejected because they fail to meet US standards.¹³⁰

In 1998, the General Accounting Office (GAO) issued a report entitled, "Food Safety: Federal Effort to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable." The report detailed FDA's struggle to inspect imported foods and found that "the ineffectiveness of FDA's approach is magnified by its inability to keep pace with rising levels of [food] imports."¹³¹

Proof abounds that the agency is increasingly unable to manage its caseload properly. In FY 2000, the number of food recalls jumped to 315, which is more than any year since the mid-1980s and 36 percent higher than the average since the agency began keeping those records 15 years ago. In each case, the recalled

¹²⁶Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹²⁷From Walter Williams, "When 'Leaner and Meaner' Mean Inefficient, Ineffective." *The Seattle Times Company*, September 25, 1998, at B5.

¹²⁸Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹²⁹*FDA Chief Financial Officer's Annual Report: FY 1999*, April 2000, at I-8. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹³⁰*Hollow Government: The Food and Drug Administration: Hearing Before the Comm. on Governmental Affairs, United States Senate*, 102d Cong. 1 (July 25, 1991) (statement of Senator John Glenn).

¹³¹From Walter Williams, "When 'Leaner and Meaner' Mean Inefficient, Ineffective." *The Seattle Times Company*, September 25, 1998, at B5.

food had gone onto store shelves before the contamination was detected.¹³² Experts are voicing concern at the increase in recalls. According to George Grob, deputy inspector general of HHS,

Any reasonable person would worry about it. If the inspection process worked really well, there would be fewer recalls. That's why you do inspections: to prevent any contamination from occurring in the first place.¹³³

In what is perhaps another symptom of an agency struggling under too many responsibilities, the number of enforcement actions pursued by the program dropped significantly as the decade of the 1990s progressed. Between FY 1991 and FY 1996, the number of injunctions dropped 80 percent and the number of seizures fell 65 percent.¹³⁴ See Figure 20.

[figure redacted]

Unfortunately, there is also substantial public health evidence that FDA can no longer meet its responsibility to assure the country of a safe food supply. As the demands on federal food inspection activities have skyrocketed, so has the incidence of serious gastrointestinal illness, which is a common measure of food poisoning. Today's levels of gastrointestinal illness are one-third higher than they were in 1948. According to the Centers for Disease Control and Prevention (CDC), food poisoning causes 5,000 deaths, 325,000 hospitalizations, and 76 million illnesses every year. CDC also notes that food causes twice as many illnesses in the United States as it was thought to cause 7 years ago.¹³⁵

Staffing. Despite the Clinton administration's commitment to a new Food Safety Initiative, the explosive

¹³²Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

¹³⁴1991 data: *FDA Fiscal Year 1993 Almanac*, at 23; 1996 data: *FDA Fiscal Year 1997 Almanac*, at 23.

¹³⁵Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

growth in the foods program’s workload has swallowed up any effects from the modest efforts to shore up the program’s staff and budget. Over the past three years, CFSAN’s staff has grown 6 percent. Because of previous agency cutbacks, however, the increases still leave the staff well below 1992 levels. The Center now conducts all of its activities with a staff of 830—about 125 fewer FTEs than it employed in 1992. In fact, since 1992, the entire Food and Drug Administration workforce has decreased 2 percent, while CFSAN has suffered cuts over six times as deep, amounting to 13 percent of its workforce.¹³⁶ The supporting field staff has increased 7 percent since 1998, yet it is still obviously struggling under a massive influx of new work.¹³⁷ See Figure 21.

Caroline Smith DeWaal, food safety director at the Center for Science in the Public Interest, summed up the effects of the overburdened staff: “The FDA is simply going from crisis to crisis and attempting to put out fires.”¹³⁸

[figure redacted]

Budget. For most of the 1990s, the food program’s budget stagnated or decreased. It reached its nadir of \$200 million in 1997, sustaining a 10 percent cut from the preceding year. Since 1997, the budget has increased by nearly \$80 million, but inflation has eroded much of the value of the gains. Although the budget grew from \$209 to \$280 million between FY 1993 and FY 2000, the increase amounted to 12 percent after inflation.¹³⁹ Considering the expansion of the program’s responsibilities during that period, it seems evident

¹³⁶1992 data: *FDA Fiscal Year 1993 Almanac*, at 60; 2000 data: FDA All Purpose Table–Current Law Program Level 2002 Estimate, posted at <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf>.

¹³⁷FDA All Purpose Table–Current Law Program Level 2002 Estimate, posted at <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf>.

¹³⁸Greg Winter, “Contaminated Food Makes Millions Ill Despite Advances,” *The New York Times* (March 18, 2001), at A1.

¹³⁹1993 data: *FDA Fiscal Year 1993 Almanac*, at 62; 2000 data: FDA All Purpose Table–Current Law Program Level 2002 Estimate, posted at <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf>. Data inflated with Bureau of Labor

that resources are stretching ever tighter and hollowing effects are increasing. See Figure 22.

[figure redacted]

FDA's resources for food safety appear especially small when compared to the sums Congress appropriates to the USDA for similar purposes. During the 1980s, there was heightened public concern over whether the government adequately inspected fish. Congress responded by almost doubling the budget for such inspections between 1990 and 1992, but even the increased budget provided only \$40 million. By comparison, USDA's meat program, which was also criticized as underfunded and excessively lax, received \$473 million during the same period.¹⁴⁰ In 1998, USDA's Food Safety and Inspection Service, which regulates meat, poultry, and eggs, received \$672 million.¹⁴¹ In that year, FDA, which is charged with regulating *all other foods*, conducted its field work on a budget of under \$119 million.¹⁴²

Summary. FDA's food safety program is struggling under the weight of crushing workload expansions, and its budget and staff resources have failed to keep pace. The activities of this division touch the lives of most Americans on a daily basis, serving as one of the most important lines of defense protecting the US from a public health crisis. With its resources spread so thin, however, the preventive functions of the foods program will erode even more than they already have. In the words of Dickson Despommier, a public health professor at Columbia University, "We are the canaries in the coal mines. The moment someone gets sick, we say, 'Don't eat that food.' It's a miracle that the system doesn't break down more."¹⁴³

Statistics Inflation Calculator, posted at: www.bls.gov.

¹⁴⁰William B. Schultz. 1992. "The Food and Drug Administration: Food, Drugs, and Medical Devices," in *Changing America: Blueprints for the New Administration*, Mark Green, ed. Newmarket Press, NY, at 571.

¹⁴¹United States Department of Agriculture FY 2000 Budget Summary, posted at: <http://www.usda.gov/agency/obpa/Budget-Summary/2000/text.html#fs>.

¹⁴²FDA All Purpose Table—Total Program Level, at www.fda.gov/oc/oms/ofm/budget/2000/netapt25.htm.

¹⁴³Greg Winter, "Contaminated Food Makes Millions Ill Despite Advances," *The New York Times* (March 18, 2001), at A1.

VIII. Animal Drugs and Feed

The Food and Drug Administration's animal feed and drugs program consists of the Center for Veterinary Medicine (CVM) and the associated field staff from the Office of Regulatory Affairs. Together, these two groups utilize premarket approvals and postmarket surveillance to ensure that animal drugs and medicated feeds are safe and effective and that the food gleaned from treated animals used as food is safe for human consumption.¹⁴⁴ Some of the higher-profile activities of the program today include efforts to prevent outbreaks of bovine spongiform encephalopathy (BSE, or "mad cow disease") in the United States and monitoring the use of antibiotics in animal feed.

The smallest of FDA's five main program centers, the Center for Veterinary Medicine withstood a 33 percent increase in premarket submissions between FY 1992 and FY 1997 at the same time that its staff shrank and its budget actually decreased (without even accounting for inflation). Sixty percent of the program's budget is devoted to salaries,¹⁴⁵ and government employees receive mandatory pay increases; thus, for the same five years in which the demand on the program's premarket approval was increasing rapidly, program managers were increasingly forced to shift operating funds to salary expenditures to cover the cost of living increases.¹⁴⁶ It appears, then, that the animal feed and drug program is experiencing the same types of hollowing pressures as other FDA program areas.

The Center for Veterinary Medicine. The main functions of the animal program's research division are to

¹⁴⁴FDA Center for Veterinary Medicine, "CVM: Structure and Responsibilities." Posted at: <http://www.fda.gov/cvm/structtxt.html>.

¹⁴⁵FDA's FY 2001 Congressional Budget Request, "Animal Drugs and Feeds Program." Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2001/andrugfeeds.htm>.

¹⁴⁶Dr. Stephen F. Sundlof, Presentation at Center for Veterinary Medicine Stakeholder Meeting, April 28, 1999. Posted at: www.fda.gov/cvm/fdama/cvmtranscript.htm.

prevent the marketing of unsafe or ineffective animal feeds, feed additives, drugs, and devices and to ensure the safety of all foods derived from animals who have been treated with any drugs or food additives. To accomplish this mission, CVM reviews four different types of drug applications: New Animal Drug Applications (NADAs), Abbreviated New Animal Drug Applications (ANADAs), Investigational New Animal Drug Applications (INADAs), and Generic Investigational New Animal Drug Applications (JINADs). During the year 2000, CVM received 28 NADAs (plus 1,286 supplements to previously-filed NADAs), 55 ANADAs (plus 195 supplements to previously-filed ANADAs), 3,422 INADs, and 194 JINADs.¹⁴⁷ Overall, this represented an increase over the 1999 CVM workload. See Figure 23.

Figure 23.¹⁴⁸

Application Type	1999 Receipts	2000 Receipts	Net Change, 1999-2000
New Animal Drug Applications	39	28	-11
Abbreviated New Animal Drug Applications	39	55	+16

¹⁴⁷FDA's FY 2002 Congressional Budget Request, at 108-109. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>

¹⁴⁸FY 1999 data: FDA's FY 2001 Congressional Budget Request. Posted at: www.fda.gov/oc/oms/ofm/budget/2001/andrugfeeds.htm. FY 2000 data: FDA's FY 2002 Congressional Budget Request, at 108-109. Posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf.

Investigational New Drug Ap- pli- ca- tions	3183	3422	+239
Generic New Animal Drug Applications	199	194	-5

New Animal Drug Applications are designed to treat or prevent disease in animals, or to make the animals better producers of food. CVM received eleven fewer NADAs in FY 2000 than it had in FY 1999 (see Figure 24), yet the time elapsing between receipt and approval increased from an average of 12 months in 1999 to 14 months in 2000.¹⁴⁹ Note from Figure 24, however, that over the course of the 1990s, the Center very successfully reduced the backlog of applications awaiting action.

[figure redacted]

On the other hand, the number of application supplements filed with the Center rose sharply from 1999 to 2000. See Figure 25. Supplemental applications are requests to alter the conditions of an existing drug approval: some are routine (for instance, if a manufacturer merely wants to change a production process), but other require a great deal of work from the Center (such as approving use of a drug for a new species or purpose).¹⁵⁰ As Figure 25 indicates, the backlog of supplements has grown substantially over the past several years.

The same can be said for new Investigational New Animal Drug Applications. As Figure 26 demonstrates,

¹⁴⁹FY 1999 data: FDA's FY 2001 Congressional Budget Request. Posted at: www.fda.gov/oc/oms/ofm/budget/2001/andrugfeeds.htm. FY 2000 data: FDA's FY 2002 Congressional Budget Request, at 108-109. Posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf.

¹⁵⁰FDA's FY 2002 Congressional Budget Request, at 108-109. Posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf.

the number of new INADAs has been falling in recent years, but the backlog has been growing. The escalating backlogs can certainly be considered a possible symptom of a hollow agency whose responsibilities are overwhelming it.

[figure redacted]

[figure redacted]

In addition to its premarket licensing process, the animal feed and drug program also monitors its regulated products after they reach the stream of commerce. One way that the program monitors the products it regulates is through the collection of Adverse Drug Reaction Reports, which detail the circumstances surrounding problems with the product. From the early to the mid-1990s, the number of Adverse Drug Reaction Reports skyrocketed over 80 percent. See Figure 27. It is possible to interpret the upsurge in adverse event reporting in two ways: either the inherent safety of the products slipped, or the incidence of reporting adverse events occurred. According to Dr. Stephen F. Sundlof, Director of CVM, the situation was the latter:

[W]e have required a lot more focused reporting in some of the product areas where there has been a lot of attention. For instance, in the area of bovine somatotropin, we require quite a lot of reporting back on that product.¹⁵¹

[figure redacted]

Staffing. As noted previously, the Clinton administration launched a Food Safety Initiative, which has led to the first sizable increase in the budget of the animal feed and drug program in years. But because the initiative is designed primarily to support grants-based research, the number of full time equivalents has not increased substantially.¹⁵² As Figure 28 demonstrates, the animal program staff dipped and then remained flat for most of the 1990s. Only in the past year or so has the program begun a tentative upswing.

As part of FDA's FY 2002 Congressional Budget Request, the animal program has requested 105 more FTEs to help carry out its BSE prevention and inspection activities, although there is no indication yet whether Congress will heed the request.¹⁵³

[figure redacted]

Budget. FDA's animal feed and drugs program conducts solid work that is vital to the nation's interests. Consider, for example, the integral role the program has performed in the prevention of BSE outbreaks in the United States, and the massive harm that the disease has caused in Europe. Yet every year FDA's animal feed and drug program is in the unenviable position of putting forth its budget request to Congress alongside requests for money to regulate AIDS and cancer drugs, new biotech breakthroughs, human foods, and other higher-profile endeavors, which often overshadow the importance of CVM's work.

At a time when budgets have been tight across most of the federal government, and when FDA has actually managed to buck trends by securing increases (pale though they may be in comparison to the workload expansions), the animal program appears to have been a ready target for reigning in FDA's budget. Between 1990 and 1999, while the overall FDA budget increased by over 50 percent, the Center for Veterinary

¹⁵²FDA Chief Financial Officer's Annual Report: FY 1999, April 2000, at I-8. Posted at: <http://www.fda.gov/oc/oms/ofm/accounting/CFO/pdf/99report.pdf>.

¹⁵³FDA FY 2002 Congressional Budget Request, posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

Medicine’s budget actually fell *without accounting for inflation*. See Figure 29.

The program’s budget has increased significantly over the past two years due to the President’s Food Safety Initiative. However, as Figure 29 also shows, in constant dollars, the gains have barely lifted the program above the levels of the early 1990s.

Summary. The backlog of various applications awaiting action within the Center for Veterinary Medicine suggest that the agency’s workload is exceeding its capacity. Only time will tell whether the recent increases in staffing and budget will be sufficient to stave off the hollowness that appears to be creeping into the organization.

[figure redacted]

IX. Center for Devices and Radiological Health.

FDA’s devices and radiological products program maintains one of the most diverse regulatory portfolios within the Food and Drug Administration, with jurisdiction over products ranging from tongue depressors to video display terminals to robotic surgery devices. The program consists of the Center for Devices and Radiological Health and a supporting field operation in the Office of Regulatory Affairs. Together, the program’s two branches are responsible for ensuring that medical devices are safe and effective, and for reducing unnecessary radiation exposure from medical, workplace, and consumer products.¹⁵⁴

Similar to other FDA program areas, the devices/radiological health program carries out its responsibilities through premarket review and licensing and postmarket surveillance. The Center considers Medical Device Premarket Approval Applications and Supplements, Medical Device Premarket Notifications, and Investiga-

¹⁵⁴Center for Devices and Radiological Health, “Overview of CDRH.” Posted at: <http://www.fda.gov/cdrh/overview.html>.

tional Device Exemption Applications. It also establishes and enforces regulations governing manufacturing practices and performance standards for the products it regulates. Furthermore, in order to monitor regulated products after they have been approved, the program operates the MedWatch reporting system, which maintains information about injuries, deaths, and other adverse experiences related to medical devices.

Activities. Over the past ten years, the annual number of applications for new medical devices has varied wildly. From FY 1990 to FY 1992, there were on average 73 petitions each year. During the next three years, the number dropped 40 percent, to an average of 40 per year. By the period of FY 1998 to FY 2000, the average had climbed back up to 64 applications per year. See Figure 30.

The number of application supplements (which are requests to alter the conditions of an existing approval) followed a similar path, dropping sharply between FY 1990 and FY 1992, and then commencing a steady four-year climb. In the past several years, though, the number of supplements has actually fallen slightly. See Figure 31.

[figure redacted]

[figure redacted]

Premarket Medical Device Approvals are reserved only for devices involving the highest risk to the patient or the newest technology. In fact, most devices are cleared for the marketplace through Premarket Notification

Approval, also known as a 510(k) submission.¹⁵⁵ Note that the number of 510(k)s is usually almost ten times higher than the number of PMDAs each year. See Figure 32.

[figure redacted]

Before the developer of a new medical device can commence a full trial to determine the product’s safety and effectiveness, the developer must gain the approval of an institutional review board and the informed consent from the individuals participating in the study. If the study presents a significant risk to the patients, the developer must also secure FDA’s authorization of an Investigational Device Exemption Application (IDE). The Center has a month from the time of its receipt to decide whether to approve or reject the application.¹⁵⁶ Figure 33 tracks the Center’s receipt and reviews of IDEs, which have risen substantially since 1994.

[figure redacted]

In addition to its premarket review and licensing activities, the device program also engages in a great deal of postmarket surveillance and field inspections. It has established the MedWatch Medical Device Report effort to monitor adverse events stemming from the use of medical devices. The reporting requirements have changed slightly over the years, so comparisons across years are not reliable; however, it is very clear that reviewing all the MedWatch reports requires a substantial commitment of agency resources. In FY 2000, the device program received reports of almost 92,000 MDR incidents, plus an additional 3,000 voluntary

¹⁵⁵Office of Device Evaluation, *Annual Report: Fiscal Year 2000*. Posted at: <http://www.fda.gov/cdrh/annual/fy2000/ode/ode-ar2000.html>.
¹⁵⁶Office of Device Evaluation, *Annual Report: Fiscal Year 2000*. Posted at: <http://www.fda.gov/cdrh/annual/fy2000/ode/ode-ar2000.html>.

reports.¹⁵⁷

Although the most recent figures are unavailable, Figures 34 and 35 hint at the growth in the number of medical device and radiological establishments subject to inspections by ORA personnel. Unsurprisingly, ORA can manage to inspect only a small proportion of the establishments each year. In FY 1998, FY 1999, and FY 2000, there were 2,002,¹⁵⁸ 2,813,¹⁵⁹ and 1,294¹⁶⁰ domestic device/radiological inspections conducted respectively.

[figure redacted]

[figure redacted]

Staffing. In 1976, Congress passed the first legislation giving FDA jurisdiction to regulate medical devices. In its Congressional Budget Request, FDA asked for enough funds to hire 1200 additional employees to accommodate the new workload, but Congress did not appropriate the money.¹⁶¹

Times are somewhat better for the program today. Now, the Center for Devices and Radiological Health and

¹⁵⁷FDA FY 2002 Congressional Budget Request, “Devices and Radiological Health,” at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁵⁸FDA FY 2000 Congressional Budget Request, “Devices and Radiological Health.” Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/fieldother.htm#devices>.

¹⁵⁹FDA FY 2001 Congressional Budget Request, “Devices and Radiological Health.” Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2001/cdrh.htm>.

¹⁶⁰FDA FY 2002 Congressional Budget Request, “Devices and Radiological Health,” at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁶¹Government Executive, Inc. “FDA on the Brink.” *Government Executive*, August 4, 1997. Posted at www.govexec.com/dailyfed/0897/080497t3.htm.

the supporting ORA field staff number under 1500.¹⁶² Since 1996, the CDRH staff has continued on a slow but steady decline, from a peak of 1,113¹⁶³ workers to 988.¹⁶⁴ The field staff has sustained proportionally deeper cuts, from nearly 600¹⁶⁵ in FY 1997 to just 483¹⁶⁶ in the last fiscal year. See Figure 36.

[figure redacted]

Interpreting the adequacy of the device program's staffing resources is not as clear cut as it is with some of the agency's other divisions, however. The indicators above suggest that the demand for CDRH's premarket approvals is actually in a moderate decline: premarket approvals, supplements, and notifications have all dropped. And while the number of IDEs has increased, the Center seems to be keeping up with the applications, reviewing as many as it receives. The data regarding the field program is incomplete; however, the number of regulated establishments falling under the program's purview increased during the mid-1990s,¹⁶⁷ while the size of the field staff conducting the inspections has shrunk in the years hence.¹⁶⁸ This suggests that the field operation may be experiencing some degree of hollowing.

[figure redacted]

¹⁶²*FDA FY 2002 Congressional Budget Request*, "Devices and Radiological Health," at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁶³*FDA Fiscal Year 1997 Almanac*, at 10.

¹⁶⁴*FDA FY 2002 Congressional Budget Request*, "Devices and Radiological Health," at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁶⁵*FDA FY 2000 Congressional Budget Request*, "Devices and Radiological Health," posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/netapt25.htm>

¹⁶⁶*FDA FY 2002 Congressional Budget Request*, "Devices and Radiological Health," at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁶⁷See *FDA FY 1993 Almanac* at 22 and *FDA Almanac FY 1997* at 56.

¹⁶⁸See *FDA FY 2000 Congressional Budget Request*, "Devices and Radiological Health," posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/netapt25.htm> and *FDA FY 2002 Congressional Budget Request*, "Devices and Radiological Health," at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

Budget. Ironically, at the same time that the number of premarket submissions to CDRH was declining in the early- to mid-1990s, its budget was actually rising. The gains were short-lived, though, as the resource level remained stagnant from FY 1997 to FY 1999.¹⁶⁹ In FY 2000, the program received a \$10 million boost, almost all of which was allocated to the Center. Figure 37 illustrates the effects of inflation on the program's budget over the past decade: the buying power of the FY 2000 budget is actually lower than all but two other years since 1993.

Summary. If FDA's medical devices and radiological health program is suffering from severe hollowing tendencies, it is not obvious from this data. It is clear that the program's workforce has decreased and its budget has remained level or dropped slightly over the past several years. But several of the most important measures of the agency's activity level have revealed a shrinking workload as well, and there do not seem to be persistent backlogs of petitions awaiting agency action or widespread complaints of inadequate inspections. There may well be hollowing trends occurring in the device program, but the characteristics of hollowing are not as obvious nor as prevalent in this program as they are in other divisions within FDA.

X. The Center for Drug Evaluation and Research

One of FDA's most crucial functions is to review all over-the-counter (OTC) and prescription medications for safety and effectiveness. This task takes two forms: premarket testing to determine whether a drug is

¹⁶⁹See *FDA FY 2000 Congressional Budget Request*, "Devices and Radiological Health," posted at: <http://www.fda.gov/oc/oms/ofm/budget/2000/netapt25.htm> and *FDA FY 2002 Congressional Budget Request*, "Devices and Radiological Health," at 124. Posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

actually fit for marketing in the United States and postmarket monitoring to ensure that the product is manufactured, packed, and labeled according to federal standards.

Activities. The Center for Drug Evaluation and Research presides over a lengthy and highly complex process for approving new drugs. On average, it requires 12 years and \$500 million to bring a new drug into public usage.¹⁷⁰ When scientists discover new chemical entities having the potential to become drugs, the chemicals are first tested on animals to determine safety and the biological response. If the results suggest that the entity is safe and effective, a drug company can submit an investigational new drug application to FDA. If FDA approves the IND, the company commences a three-phase clinical trial to evaluate safety and efficacy, while the number of patients using the drug gradually increases. About 70 percent of the drugs undergoing clinical trials complete Phase I. A third finish Phase II, while just 27 percent complete Phase III. Only at the conclusion of Phase III can a company submit a New Drug Application to CDER.¹⁷¹

Over the past twenty years, the pharmaceutical industry's spending on drug research and development increased seven-fold, from \$5 billion to \$35 billion per year.¹⁷² This has translated into a steady influx of applications for various kinds of approvals at the Center for Drug Evaluation and Research, the largest of FDA's 5 centers.¹⁷³ The number of active Investigational New Drug Applications has risen 27 percent since FY 1990, from 9,506 to 12,030.¹⁷⁴ See Figure 38. The number of New Drug Applications grew 54 percent

¹⁷⁰Hearing on a Medicare Prescription Drug Benefit, United States Senate Committee on Finance, 106th Cong. (March 22, 2000) (statement of Alan F. Holmer, President and Chief Executive Officer, Pharmaceutical Research and Manufacturers of America). Posted at: <http://www.senate.gov/~finance/3-22phrm.pdf>.

¹⁷¹C. Daniel Mullins, Francis Palumbo, and Bruce Stuart. "Projections of Drug Approvals, Patent Expirations, and Generic Entry from 2000 to 2004." Report prepared for the Department of Health and Human Services' Conference on Pharmaceutical Pricing Practices, Utilization and Costs (August 8-9, 2000). Posted at: <http://aspe.hhs.gov/health/reports/Drug-papers/Mullins-Palumbo%20paper-final.htm>.

¹⁷²Food and Drug Administration FY 2001 Performance Plan. Accessible at: <http://www.fda.gov/ope/fy01plan/parts01.html>.
¹⁷³Center for Drug Evaluation and Research, "From Test Tube to Patient: Improving Health through Human Drugs." (1999 version), posted at: <http://www.fda.gov/cder/about/whatwedo/testtube-1.pdf>.

¹⁷⁴1990 statistic: *FDA Almanac, Fiscal Year 1993*, at 29. 2000 statistic: *FDA's Fiscal Year 2002 Congressional Budget Request*, posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

during the same period, from 69 to 106.¹⁷⁵ See Figure 39.

[figure redacted]

figure redacted

Each year, as part of its premarket NDA approval process, the Center encounters a number of New Molecular Entities (NMEs), which are substances that have never been approved in the United States for use in a drug product either as the only ingredient or as part of a combination of ingredients.¹⁷⁶ NMEs require exhaustive testing, and their numbers are rising rapidly. Figure 39 demonstrates the large increase in the incidence of NMEs under review at CDER today versus years past. The average annual number of NMEs approved between 1995 and 2000 is nearly three times higher than it was in the 1960s.¹⁷⁷

[figure redacted]

The generic drugs division has become an area of particular accomplishment for the Center. From 1993 to 2000, the number of generic drug approvals rose 36 percent while the average approval time fell from 40.4 months to 22.3 months.¹⁷⁸

¹⁷⁵1990 statistic: *FDA Almanac, Fiscal Year 1993*, at 29. 2000 statistic: *FDA's Fiscal Year 2002 Congressional Budget Request*, posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.pdf>.

¹⁷⁶*FDA's Quarterly Report, 4th Quarter 1994*, at 43.

¹⁷⁷Center for Drug Evaluation and Research, *Improving Public Health Through Prescription Drugs: Center for Drug Evaluation and Research Fiscal Year 1997 Report to the Nation*, at 5-6. Posted at: www.fda.gov/cder/reports/rptntn97.pdf.

¹⁷⁸*FDA's Fiscal Year 2002 Congressional Budget Request* at 79, posted at: <http://www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/LangDevices.p>

[figure redacted]

FDA's field responsibilities are no less daunting. Currently, over 18,000 establishments in the U.S. manufacture, test, pack, or label human drug products, and FDA's drug field operation is required to inspect each of the facilities at least once every two years. An additional 1,100 foreign establishments receive intermittent inspections.¹⁷⁹

The drug program's field staff is housed in offices in 172 different locations across the country, and it completed 3,661 inspections in 3,230 domestic establishments in FY 1998. It also conducted 356 inspections of 323 establishments overseas.¹⁸⁰

The field staff's inspections and the CDER's surveillance of adverse reaction reports provide the basis for the drug program's enforcement actions, which include drug recalls and drug withdrawal. As Figure 41 demonstrates, the number of Adverse Reaction Reports to the drug program has risen steadily during the 1990s.

[figure redacted]

Drug recalls and drug withdrawals are two means of removing unsafe pharmaceuticals from the market. A drug withdrawal is essentially a revocation of a drug's approval, often based on discoveries of adverse effects after the drug has become marketed more widely than in clinical trials. Drug recalls occur when

¹⁷⁹FDA Center for Drug Evaluation and Research, "An Inside Look at FDA On-Site," posted at: <http://www.fda.gov/cder/about/whatwedo/testtube-7.pdf>.

¹⁸⁰FDA Center for Drug Evaluation and Research, "An Inside Look at FDA On-Site," posted at: <http://www.fda.gov/cder/about/whatwedo/testtube-7.pdf>.

particular batches of a drug are unfit for marketing: perhaps they are mislabeled, or there was a defect in the processing, for example. Drug recalls are not a revocation of the drug's approval.

Prescription drug recalls spiked at 581 in 1991, but they gradually fell to 177 in 1998. Unfortunately, the number rose to 352 again in 1999. Over the course of the decade, the number of recalls of over-the-counter medication remained fairly stable, ranging from 34 in 1997 to 102 in 1994. See Figure 42.

[figure redacted]

Between 1995 and 1999, CDER withdrew four drugs from the market; from 1990 to 1994 it had only withdrawn two. However, the increase in the total number of approvals means that the proportion of withdrawals has increased only slightly.¹⁸¹ See Figure 43.

[figure redacted]

Staffing. One of the most valuable resources of FDA's drugs program is its highly talented staff. Approximately half of CDER's employees are physicians or scientists.¹⁸² Since 1992, the staff of the Center for Drug Evaluation and Research has grown by 364 FTEs, many of which are now funded through industry-backed user fees. This represents a 26 percent increase over 9 years. Field staff have fared worse, losing 17 percent of their staff just since 1997.¹⁸³ See Figure 44.

¹⁸¹Center for Drug Evaluation and Research, *Improving Public Health Through Human Drugs: CDER's Annual Report to the Nation 1999*, at 27. Posted at: www.fda.gov/cder/reports/rtn99.pdf.

¹⁸²Center for Drug Evaluation and Research, "From Test Tube to Patient: Improving Health through Human Drugs." (1999 version), posted at: <http://www.fda.gov/cder/about/whatwedo/testtube-1.pdf>.

¹⁸³1997 statistic: *FDA Fiscal Year 1999 Congressional Budget Request*, FDA All Purpose Table—Total Program Level, posted

[figure redacted]

Budget. User fee revenues have helped CDER respond to some of the more dire unmet needs in its division, but the budget remains a serious problem for the agency. Inflation has eaten away most of CDER's budget increases over the past decade. For example, in the past five years, after accounting for inflation, the CDER budget rose only five percent.¹⁸⁴ See Figure 45.

Summary. The workload of FDA's drug program increased substantially over the past decade—well beyond the small increases in staff and budget. While some indicators suggest that the program is becoming more efficient and effective, citing shorter review periods and higher drug approval rates, others argue that those results stem from an agency cutting corners as a response to severe political pressure and resource strains.¹⁸⁵ Regardless, it is clear that the regulated markets are expanding rapidly, while the agency's budget and staffing levels have not kept up. If the trend persists, we risk the safety of our drug supply.

[figure redacted]

XII. ANALYSIS.

The foregoing examination of FDA's responsibilities and its resources can lead to some basic generalizations about hollow government. For example,

- *The likelihood of hollow government is inversely related to the perceived importance of the*

at: <http://www.fda.gov/oc/oms/ofm/budget99cj.htm>.

2000 statistic: *FDA Fiscal Year 2001 Congressional Budget Request*, FDA All Purpose Table–Total Program Level, posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf

¹⁸⁴1995 statistic: *FDA Almanac Fiscal Year 1996*, at 15. 2000 statistic: *FDA Fiscal Year 2001 Congressional Budget Request*, FDA All Purpose Table–Total Program Level, posted at: www.fda.gov/oc/oms/ofm/budget/2002/CJ2002/apt.pdf

¹⁸⁵See, for example, the recent Pulitzer Prize winning feature: David Willman, "The New FDA: How a New Policy Led to Seven Deadly Drugs." *Los Angeles Times* (December 20, 2001), at A1.

agency's activities. As a nation, we want more services from the government than we are willing to pay for. The federal budget cannot stretch far enough to ensure that every task that we demand of it will be performed well, which guarantees that some degree of hollow government is inevitable. One of the important tasks of policymakers, then, is to properly corral the hollowness in the areas of the government that will result in the least harm.

Obviously, policymakers will be more vigilant about seeking out and ameliorating hollowness in agencies whose activities are considered high public priorities. For example, the vast majority of the public would consider ensuring the safety and efficacy of human drugs much more important than guaranteeing the safety and efficacy of animal feed or drugs. Not surprisingly, the evidence of resource strain is starker in the Center for Veterinary Medicine than in the Human Drugs Program.

- *The political system establishes incentives for members of Congress and the President to engage in some level of “hollowing.”* Recall that Congress passed 24 new laws imposing responsibilities on FDA during the 1980s, at a time when the agency’s staff and budget were in a slump. Members of Congress win the favor of the public by passing noble and sweeping legislation aimed at solving the societal problems or responding to crises. It makes them look decisive, proactive, and energetic—characteristics voters love. Yet Congress is not required to provide funding for new responsibilities that it heaps on agencies. Members of Congress are rarely criticized for sponsoring or supporting legislation that provokes hollowing effects. After the legislation is enacted, the news story dies down for a long time. Years down the road, if anyone ever investigates whether the statute is being adequately carried out or enforced, the agency will typically be the target of criticism, not the member of Congress who voted to increase the jurisdiction of the agency.

- *Decisions about FDA’s overall level of resources and the scope of its responsibilities are made in a political process, which leads to different outcomes than if they were made on other*

bases. This can result in hollowing. FDA appropriations and substantive laws result from a political and legislative process that involves negotiations among people who have very different priorities. That is not to say that a political process is not a rational process—legislative bargains are highly calculated attempts to optimally suit the expressed needs and desires of interest groups, the public, and the legislators themselves, even if those needs and desires are based on incomplete information or are colored by crisis.

But the outcomes of a legislative process are not identical to those that would result if the process were more fully based on science, medicine, economics, or management studies. A political process is particularly prone to allocating disproportionate resources to programs and activities that respond to issues attracting significant public attention—even if those activities are not the ones that provide the most public good.

The legislative process, and in turn, resource allocation for agencies like FDA, is particularly affected by the loud cries of activists or the exigencies of a perceived crisis. After cyanide-laced Tylenol created a nationwide panic, Congress passed legislation aimed at preventing such tampering. Even if the new law accomplished much good, it was not adopted after a careful comparison of whether the resources it demanded could be better put to use in other fashions. Thus, the very process by which resource allocations decisions are made can lead to hollowing trends in government.

- *Sometimes decisionmakers deliberately encourage hollow government in order to advance other political goals.* Killing government programs can be a very politically costly move. For instance, Congress established the Council on Environmental Quality within the Executive Office of the President in the late 1960s to respond to the public's growing concern about the environment. This tiny office is thought to duplicate some of the functions of the Environmental Protection Agency and the Department of the Interior, so Presidents Carter, Reagan, and Clinton have all tried unsuccessfully to eliminate it. Each time the various Presidents targeted this seemingly insignificant office, they were attacked with a hail of

criticism from environmental activists and were forced to back away.¹⁸⁶

Because supporters of even the smallest government programs can often galvanize strong political opposition to the elimination of the organization, politicians tend to avoid the trouble by starving an agency rather than killing it. In many ways, this characterizes how President Reagan handled his opposition to many of the regulatory burdens that the FDA placed on industry in the 1980s. Instead of pushing for the repeal of laws or instructing his FDA Administrator to close some of the agency's activities, which would have invited criticism from consumer groups and some in the medical field, the President slashed the budget and staff of the organization, ensuring that it could do less work.

Furthermore, after agencies have been starved for a period of time, their reputations suffer. They become viewed as bumblerers or inept managers because they are accomplishing so little. At that point, the lack of results can make it even easier to persuade Congress to reduce the agency's budget.

XIII. CONCLUSIONS.

In broad terms, it appears that FDA has experienced two different varieties of hollowing during the past two decades. During the Reagan administration, FDA, like many programs, was eyed for staff reductions and sharply limited budgets as a means of reducing the regulatory burden on American industry and restraining the federal budget. The hollowing in this instance was intentional and calculated.

A somewhat different form of hollowing took place in the 1990s. While budgetary pressures remained acute for much of the decade, the national attitude toward government regulation seemed to soften slightly. Then,

¹⁸⁶Ann Devroy, "Clinton Announces Plan to Replace Environmental Council," *The Washington Post* (February 9, 1993), at A6. Discusses attempts on the part of Clinton, Reagan, and Carter to eliminate the agency, which still exists. See office's website at: www.whitehouse.gov/ceq.

the impetus for the hollowing appears to be the explosive growth of FDA-regulated industries rather than an outright hostility towards regulation itself. As early as January 1998, then-Lead Deputy Commissioner Michael A. Friedman stated that the agency's workload was expanding at a rate of 12 percent per year—which means that FDA's responsibilities double every six years.¹⁸⁷ Even though FDA has been spared from much of the federal downsizing efforts and its budget has grown by a respectable 50 percent over the past decade, the increases are woefully inadequate to keep pace with fields expanding as quickly as biotech, transgenic crop development, and AIDS research have, for example.

Even though the intentions of Congress and the administration may have been different in the two decades, the result has been nearly the same: an agency whose mission exceeds its capacity.

James Benson, FDA's Acting Commissioner in 1990, aptly summed up the erosion his organization was experiencing and the toll on its work:

[P]eople expect more than we are capable of delivering. Paradoxically, we live in an age when people want less government, have less respect for Federal workers, yet, at the same time, demand more and better protection from the risks of everyday life.... At the heart of this issue is whether we've been able to keep pace with a rising tide of demands. The simple answer is "no."¹⁸⁸

FDA is one of the most important regulatory agencies in the country. It has always served as a staunch line of defense guarding the American public from public health catastrophes and consumer fraud. Despite a few isolated incidents of scandal, FDA has earned a reputation for careful, impartial, and highly-esteemed work.

¹⁸⁷"FDA Faces Performance Challenges: Friedman Cites Resource Constraints." *The Pike: a publication of the Center for Drug Evaluation and Research*, (January 15, 1998), at 1.

As a result, the United States enjoys the safest food and drug supply in the world.

But the evidence is clear that the agency cannot continue to offer the same quality of protection with its resources under such severe strain. Although nominal attempts were made to shield FDA from some of the budget cutbacks of the 1990s, the gulf separating its capacity and its responsibilities expanded as the volume and complexity of almost all of FDA's regulated markets grew off the charts over the past ten years. Unless Congress and the President can devise a way to direct more resources (whether public or private) to FDA, the agency's long-term health is in jeopardy.

We have seen the results of hollow government in other governmental arenas: billions lost to fraud in the Medicare program and the savings and loan scandals, environmental disasters like the Exxon *Valdez* incident, and elderly citizens losing their Social Security benefits because of unreliable intermediaries at the Social Security Administration. Even these disasters pale in comparison to the catastrophe that could ensue if the Food and Drug Administration is allowed to continue its present trend of decay.